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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,903	03/10/2004	Yuji Yamamoto	25142-0002001	3373

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EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
08/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/797,903	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14,16-18 and 20-37* is/are pending in the application.

4a) Of the above claim(s) *16,21,28 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,14,17,18,20,22-27,29-34,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1 sheet, 2/26/2009; 1 sheet, 6/23/2009.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed 6/23/2009, has been received and entered into the present application. Accordingly, prosecution has been reopened.

Applicant's amendment filed 6/23/2009 has been received and entered into the present application.

Claims 12, 14, 16-18, 20-37 are pending. Accordingly, claims 12 and 16-17 are currently amended, claims 20-37 are newly added. Claims 16, 21, 28 and 35 are withdrawn for being drawn to non-elected subject matter.

As reflected by the attached, completed copy form PTO/SB/08A (two pages total), the Examiner has considered the cited reference.

Applicant is reminded of the specie election of small cell lung cancer and 4-(3-chloro-4-(cyclopropylaminocarbonyl)aminophenoxy)-7-methoxy-6-quinolinecarboxamide filed on 8/15/2007 and 9/27/2007, respectively.

Applicant's arguments, filed 6/23/2009 have been fully considered. Rejections not reiterated from the previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claims 12, 14, 17-18, 20, 22-27, 29-34 and 36-37 are currently under examination and the subject of this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14, 17-18, 20, 22-27, 29-34 and 36-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention.

Present claims are directed to a method for treating a cancer in a patient, comprising determining if the patient's cancer expresses c-Kit kinase or a mutant c-Kit kinase and if the cancer is determined to express c-Kit kinase or a mutant c-Kit kinase by administering to a patient a compound represented by formula (I).

The specification and claims as originally filed fail to provide adequate written description for the newly amended limitation of:

(1) determining if the patient's cancer expresses c-Kit kinase or a mutant c-Kit kinase;

(2) if the cancer is determined to express c-Kit kinase or a mutant c-Kit kinase;

(3) a cell that is a mast cell or an eosinophil

Upon review of the disclosure, no such limitations, (1) determining if the patient's cancer expresses c-Kit kinase or a mutant c-Kit kinase; (2) if the cancer is determined to express c-Kit kinase or a mutant c-Kit kinase; (3) a cell that is a mast cell ro a eosinophil were found. While it is recognized that adequate written description of a limitation is not required to be stated in *haec verba* in the specification or claims as originally filed, adequate written support for all claim limitations must arise from either an

explicit or implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention.

MPEP 2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement, does the description clearly allow persons of ordinary skill in the art to recognize that he or she invention what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter," *Ralston Purina Co. v. Far-Mar-Co., Inc.* 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))… Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a)

Claims 12, 14, 17-18, 20, 22-27, 29-34 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funahashi et al. (WO 02/032872, cited by Applicant) in view of Hibi et al. (reference provided by Applicant) in light of CancerCare, www.lungcancer.org, 2009).

Examiner is using the Japanese WO 02/032871 document for its publication date and is providing US Patent 7, 253, 286 as an English language equivalent of that document.

Funahashi et al. disclose the elected compound: claim 1 discloses R_1 and R_2 as hydrogen (claim 1), R^{a12} is the cyano taught by the formula in column 904, line 40, second compound, (claim 1), Y^{a1} is represented by the formula in column 903, line 35, first compound, where W^{31} and W^{32} are each independently an optionally substituted carbon atom (claim 1) and Z^{12} is an alicyclic hydrocarbon group (claim 1). This particular combination teaches the compound elected by Applicant. Additionally, Funahasi et al. describes utility of the elected compound having angiogenesis inhibitory action (column 2, lines 63-67) and tumor cell proliferation (column 83, last line) inhibitory action in treatment of diseases including as a "pulmonary treatment agent" (column 34, line 22). Further, the agent can be used for the treatment of lung cancer (column 22). Further, the compound can be administered orally and parenterally (column 83, lines 23-29).

CancerCare teaches that there are two types of lung cancer, non-small cell lung cancer and small cell lung cancer.

Hibi et al. discloses that lung cancer cells have been known to produce autocrine growth factors which include gastrin-releasing peptide, leading the author to study c-kit expression in small cell lung cancer (page 2295, left column, paragraph 2). The researchers conclude that c-Kit expression is present in small cell lung cancer.

One of ordinary skill in the art at the time of the invention would have found it prima facie obvious to employ the results found in Hibi et al. with a reasonable expectation of success because of the clear antiproliferative activity of the elected compound (Funahasi et al.) in a variety of tumor cell lines including the elected small cell lung cancer. Motivation to do so flows logically since Hibi et al. teaches that c-Kit expression is found in small cell lung cancer and Funahasi et al. teach the elected compound as an effective treatment for lung cancer. Given that c-Kit activity is present in small cell lung cancer, per Hibi et al., one would further be motivated to determine whether c-Kit kinase is being expressed.

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if the inhibition of c-Kit kinase was not itself recognized as a pharmacological effect of administering the elected compound of Funahasi et al. to a patient exhibiting proliferation of cancer cells such as small cell lung cancer, such an effect (treatment of lung cancer including small cell lung cancer) is already known in the prior art.

Though new properties of a compound are no doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 103 is based upon the therapeutic applications and effects of the compounds, not the mechanisms or properties by which they exert such a therapeutic effect.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614